Proposed Re-evaluation Decision PRVD2010-16

Copper and Zinc Naphthenate Salts

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of the wood and material preservatives copper and zinc naphthenate salts, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration for the sale and use of products containing copper and zinc naphthenate salts in Canada.

An evaluation of available scientific information found that products containing copper and zinc naphthenate salts do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of the naphthenate salts uses, new risk-reduction measures must be included on the labels of all products. Additional data are being required as a result of this re-evaluation.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

This proposal affects all end-use products containing copper and zinc naphthenate salts registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for naphthenate salts and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of naphthenate salts.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Copper and zinc naphthenate salts, two of the active ingredients in the current re-evaluation cycle; have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2007 RED, the USEPA concluded that copper and zinc naphthenate salts were eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Are Copper and Zinc Naphthenate Salts?

Copper naphthenate is a fungicide and insecticide registered for use as a wood and material preservative to control fungal rot, mildew, wood decay and wood-boring insects (including termites, carpenter ants). For preservation of joinery wood products, it can be applied in industrial settings using a spraybox, flow coating or via dipping. For remedial wood treatment, copper naphthenate can be applied by commercial workers to wood surfaces (including shingles, porches, steps and fence posts) using a brush, and to industrial wood products (including in-service utility poles, bridge timbers) using a brush, roller, trowel, pressurized applicator or impregnated fabric. As a material preservative, copper naphthenate can be applied by commercial workers to exterior fabric (including tents, awnings, ropes) by dipping. Homeowners can apply ready-to-use products to wood surfaces and exterior fabric (for example, awnings) by brush.

Zinc naphthenate is a fungicide registered for use as a wood and material preservative to control fungal rot, mildew and wood decay. There are no commercial products containing zinc naphthenate registered in Canada. Homeowners can apply ready-to-use products to wood surfaces and exterior fabric by brush.

Health Considerations

Can Approved Uses of Copper and Zinc Naphthenate Salts Affect Human Health?

Copper and zinc naphthenate salts are unlikely to affect your health when used according to the revised label directions.

People could be exposed to the naphthenate salts by working as a mixer/loader/applicator and while coming in contact with treated wood and/or fabric. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that copper and zinc naphthenate salts were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation and similar risk-reduction measures are required.

Environmental Considerations

What Happens When Copper and Zinc Naphthenate Salts Are Introduced Into the Environment?

Copper and zinc naphthenate salts are unlikely to affect non-target organisms when used according to the revised label directions.

Aquatic organisms could be exposed to copper and zinc naphthenate salts in the environment. Environmental risk is assessed by the risk quotient method - the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. In this screening level assessment, the resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas, a risk quotient greater than the level of concern indicates some potential risks of concern.

The USEPA concluded that copper and zinc naphthenate salts are unlikely to adversely affect the environment. General advisory environmental label statements were required by the USEPA. These conclusions apply to the Canadian situation and similar advisory label statements are proposed by the PMRA.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of the naphthenate salts, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Additional personal protective equipment for workers handling copper naphthenate products as well as individuals handling domestic products
- Reduction of the maximum guarantee of zinc naphthenate in domestic products
- Limit the use of copper naphthenate-treated fabric to non-residential areas
- Removal of the fabric use from domestic product labels
- Hazard label statements for all end-use products

Environment

- Additional advisory environmental label statements

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix I lists all data requirements.

Next Steps

Before making a final re-evaluation decision on copper and zinc naphthenate salts, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Copper and zinc naphthenate salts are pesticides registered for use as wood and material preservatives to control fungal rot, mildew, wood decay and wood-boring insects (including termites, carpenter ants).

Following the re-evaluation announcement for copper and zinc naphthenate salts, the registrant of the technical grade active ingredients (a.i.) in Canada indicated their intention to provide continued support for all uses included on the labels of commercial and domestic class end-use products in Canada.

The PMRA used recent assessments of copper and zinc naphthenate salts from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for copper and zinc naphthenate salts, dated 2007 as well as other information on the regulatory status of copper and zinc naphthenate salts in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredients, Their Properties and Uses

2.1 Identity of the Technical Grade Active Ingredients

Common name		Copper Naphthenate (CUN)	Zinc Naphthenate (ZNN)
Function		Fungicide, insecticide, material preservative, wood preservative	Wood preservative, fungicide
Chemical family		Naphthenate salts	Naphthenate salts
Chemical name			
1	**International Union of Pure and Applied Chemistry (IUPAC)**	copper naphthenate	zinc naphthenate
CAS Registry Number		1338-02-9	12001-85-3
Molecular formula		$Cu(RCOO)_2$ (R is typically an alkyl substituted cyclopentyl or cyclohexyl group, from C_{10} to C_{20})	$Zn(OOCR)_2$

Common name	Copper Naphthenate (CUN)	Zinc Naphthenate (ZNN)
Structural formula	various	Not provided
Molecular weight	~363 to ~663 amu	variable, between 365 and 665 amu

Copper naphthenate technical grade products are not expected to contain any impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances. Additional information will be requested from the Registrants regarding the impurity profile of the zinc naphthenate technical grade product.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Copper Naphthenate	Zinc naphthenate
Vapour pressure	Negligible	Not determined
UV–visible spectrum	λ_{max} 260, 670 nm strong absorption from 200 to 300 nm, 600 to 800 nm	Not provided
Solubility in water	46 ppm (46 mg/L)	<0.1% by weight
***n*-Octanol–water partition coefficient**	log K_{ow} ~ 4.1 (estimated)	Not applicable

2.3 Comparison of Use Patterns in Canada and the United States

In Canada, copper and zinc naphthenate salts are registered for use as wood and material preservatives. There are 24 pest control products containing copper naphthenate (3 technical grade, 9 commercial and 12 domestic) and 12 products containing zinc naphthenate (1 technical grade and 11 domestic) currently registered in Canada (Appendix II).

Commercial products containing copper naphthenate can be used:

- For joinery wood preservation in wood treatment facilities as a 15% solution using a spraybox, flow coating or a diptank.
- For remedial treatment of wood surfaces (including shingles, porches, steps and fence posts) as a 15% treatment solution by brush only.
- For remedial treatment of exterior industrial wood products (including in-service utility poles, posts, bridge timbers) as a 20% treatment solution using a brush, roller or a pressure pump, as a 2% (copper as elemental) paste using a trowel, grease gun or other pressurized applicator, and as a pre-manufactured wrap (fabric impregnated with 2% copper).

- For preservation of industrial fabric (including tents, awnings, tarpaulins, canvases products and ropes) as a 15% treatment solution by immersion in a diptank.

Ready-to-use domestic-class products containing a maximum of 8% copper naphthenate or 25% zinc naphthenate can be applied by homeowners to wood surfaces or exterior fabric (for example, awnings) using a brush.

The American and Canadian use patterns were compared. At the time of the RED document, copper and zinc naphthenate salts were registered in the US for use as wood and material preservatives applied as a treatment solution containing a maximum of 25 to 32% active ingredient. Based on comparison of the US and Canadian use patterns, formulations and application methods, it was concluded that the USEPA RED for copper and zinc naphthenate salts is an adequate basis for the re-evaluation of uses of copper and zinc naphthenate salts in Canada.

All current uses are being supported by the registrants and were, therefore, considered in the re-evaluation. Appendix II lists all products containing copper or zinc naphthenate salts that are registered as of March 18, 2010, under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with copper and zinc naphthenate salts met the safety standard under the *American Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the revised product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

Exposure to copper and zinc naphthenate salts may occur through consumption of water, through residential exposure, while working as a mixer/loader/applicator or while coming in contact with treated products. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers).

The toxicological endpoints used for the human health risk assessment are summarized in Appendix III.

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

The USEPA considered a target MOE of 100 (10 fold interspecies and 10 fold intraspecies variation) for the dermal route of exposure to be adequate for the occupational risk assessment. For the inhalation route of exposure, the USEPA applied an additional 10 fold uncertainty factor (for route-to-route extrapolation) which resulted in a target MOE of 1000.

Based on the use pattern it was determined that workers can be exposed to copper naphthenate when mixing, loading or applying the pesticide, and when handling treated wood or fabric.

3.1.1.1 Handler Exposure and Risk

Based on the American use pattern, the USEPA determined that there were several potential exposure scenarios for occupational handlers of products containing copper and zinc naphthenate salts. Since a dermal endpoint of concern for copper naphthenate was not established, the USEPA's occupational risk assessment addressed only inhalation exposure to copper naphthenate and both dermal and inhalation exposures to zinc naphthenate.

In Canada, only copper naphthenate products are registered for use in commercial settings, therefore, only scenarios pertaining to inhalation exposure to copper naphthenate will be discussed in this section. Among the scenarios assessed in the 2007 RED, the following were applicable to the Canadian use pattern:

- The chemical operator of a spraybox system in the wood treatment facility.
- The diptank operator in the wood treatment facility; a scenario encompassing flow coating application to wood and dipping/immersion operations for textiles.
- The applicator using a brush/roller to apply products to wood surfaces (including in-service utility poles); a scenario encompassing other potential application methods such as a trowel, injection and wrap.

The potential exposures of the chemical and diptank operators were assessed using surrogate exposure data from the Didecyl Dimethyl Ammonium Chloride (DDAC) study and assuming a 25% a.i. (by weight) treatment solution. While the potential exposure of the applicator using a brush/roller was estimated using unit exposure values from the Pesticide Handler Exposure Database (PHED) and assuming a 25% a.i. treatment solution and 19.3 kg of product handled per day.

The USEPA reported short-/intermediate-/long-term inhalation MOEs for both the diptank operator and chemical operator scenarios above the target MOE of 1000, indicating no risk of concern. For applicators using a brush/roller or an airless sprayer, inhalation MOEs were below 1000 thus, indicating a risk of concern.

In animal studies, the RED reports that both naphthenate salts demonstrated a moderate to severe skin irritation potential as well as, slight to moderate eye irritation. The naphthenate salts are also potential skin sensitizing agents. The 2007 RED cited human incident reports involving inhalation exposure to copper naphthenate vapours. Symptoms included nausea, headache, dizziness, sore throat, chest tightness and coughing.

Given the above, the PMRA is proposing a respirator for all workers applying copper naphthenate products by brush as well as, a label statement prohibiting the use of an airless sprayer for general wood preservation. Additionally, the PMRA is proposing personal protective equipment (PPE) consisting of coveralls over a long-sleeved shirt and long pants, chemical resistant footwear, chemical resistant gloves and goggles for all workers handling copper naphthenate products. The proposed label amendments are listed in Appendix IV.

3.1.1.2 Postapplication Exposure and Risk

The postapplication occupational risk assessment considered exposure of workers handling treated wood or fabric and/or involved in clean-up activities. Among the scenarios assessed in the 2007 RED for the wood use, the following were considered relevant to the Canadian situation:

- Graders – workers positioned right after the spraybox who are responsible for grading the wood by hand (to detect faults);
- Construction workers – workers installing treated wood such as door and window frames;
- Clean-up – workers performing clean-up duties in commercial wood treatment facilities;

The USEPA assessed the postapplication inhalation exposure of workers using surrogate exposure data from the DDAC study. The reported inhalation MOEs for clean-up activities, for construction workers and graders were above the target MOE of 1000, indicating no risks of concern.

For the material preservation uses of copper naphthenate, the USEPA determined that postapplication inhalation exposure of workers handling treated fabric is expected to be negligible.

The RED adequately addressed the potential postapplication exposure scenarios associated with the Canadian uses of copper naphthenate. No further mitigation measures are proposed by the PMRA.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the MOE approach described in section 3.1.1.

In Canada, individuals may be exposed to naphthenate salts while applying domestic-class products to wood or fabric using a brush and when coming in contact with treated wood or fabric. In addition, children may be exposed to naphthenate salts through incidental oral exposure (mouthing treated textiles or hand-to-mouth activity).

Residential handler exposure
The potential dermal and inhalation exposure of individuals applying by brush domestic-class product to wood or fabric was assessed using unit exposure values from the Canadian PHED tables. Assumptions included a use solution containing a maximum guarantee of 25% a.i. (by weight), 7.6 L of stain was used per day and gloves. The estimated exposure dose resulted in an inhalation MOE above the target MOE of 1000, thus, indicating no risk of concern. For the dermal route of exposure, however, a risk of concern was identified given that the MOE was less than the target MOE of 100.

In order to reduce homeowner exposure, the PMRA is proposing to reduce the maximum guarantee in domestic products to 16% zinc naphthenate (2% zinc as elemental) and to add a label statement requiring a long-sleeved shirt, long pants, socks and shoes, and rubber gloves on all domestic-class product labels.

As noted in section 3.1.1.1 above, animal studies indicate potential skin irritation and sensitization properties of copper naphthenate. Further, the 2007 RED reports incidents involving skin rashes following dermal exposure to copper naphthenate products. On this basis, personal protective equipment similar to that proposed for zinc naphthenate products above is also proposed for products containing copper naphthenate. The proposed label statements are listed in Appendix IV.

Postapplication exposure to treated wood and fabric
The potential short-term postapplication dermal exposure of children and adults to zinc naphthenate-treated textiles was assessed by the USEPA. It was assumed that individuals will be sleeping on a tent floor wearing short pants, short-sleeved shirt or just undergarments. Further, it was assumed that 5% of zinc naphthenate residues will be transferred from the fabric to the skin. Based on these assumptions, the estimated exposure dose resulted in a dermal MOE above the target of 100, indicating no risk of concern. There are no commercial products containing zinc naphthenate registered in Canada; therefore, the USEPA risk assessment does not apply to the Canadian situation. The Canadian domestic-class products containing zinc naphthenate are registered for use on exterior fabric (for example, awnings); however, according to label directions, these products are not to be used for application to fabric where prolonged skin contact may occur. On this basis, dermal exposure to zinc naphthenate in residential settings is expected to be negligible and no further mitigation measures are required.

The potential short-term postapplication dermal exposure of children to treated wood was assessed using surrogate data from the DDAC study. The estimated exposure dose resulted in an MOE above the target MOE of 100, indicating no risk of concern. No further mitigation measures are proposed by the PMRA.

The potential incidental oral exposure of children to naphthenate salts resulting from "mouthing of textiles" activity was assessed by the USEPA assuming a treatment solution containing 11% active ingredient. The estimated exposure dose resulted in an oral MOE below the target MOE of 100, indicating a risk of concern for children. The PMRA is proposing to limit the use of commercially-treated textiles to non-residential areas only. In addition, the PMRA is proposing to remove the fabric use from the copper and zinc naphthenate domestic product labels. The proposed label statements are listed in Appendix IV.

For potential incidental oral exposure of children to naphthenate salts resulting from "hand-to-mouth" activity, the USEPA used surrogate exposure data from the DDAC study. The estimated exposure dose resulted in an oral MOE above the target MOE of 100 thus, indicating no risk of concern for this activity. No further mitigation measures are proposed by the PMRA.

3.1.2.2 Exposure from Food and Drinking Water

The USEPA did not conduct dietary and drinking water risk assessments for copper and zinc naphthenate salts because:

- There were no dietary endpoints of concern for copper and zinc naphthenate salts;
- Dietary exposure was not expected based on the registered use pattern;
- Copper and zinc naphthenate salts were not expected to come in contact with drinking water.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to copper and zinc naphthenate salts in residential settings. The USEPA determined that a route-specific approach for an aggregate exposure assessment is appropriate because endpoints selected for dermal and incidental oral route of exposure were based on route-specific studies resulting in different effects.

Two potential aggregate exposure scenarios were identified in the 2007 RED.

- For adults, aggregate exposure consisting of the handler exposure (application of wood/fabric preservative) and postapplication exposure to treated wood and fabric.
- For children, aggregate exposure consisting of postapplication exposure to treated wood and fabric.

The USEPA concluded that it was highly unlikely that an adult will be applying a product and come in contact with treated wood and fabric on the same day, therefore, an aggregate exposure of an adult should not be of concern. For children, since a single scenario was identified for each route of exposure (dermal or incidental oral), an aggregate risk assessment was not required.

The USEPA conclusions are considered relevant to the Canadian situation. On this basis, no mitigation measures are proposed by the PMRA.

3.1.3 Cumulative Effects

The USEPA has not determined whether naphthenate salts have a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that naphthenate salts do not share a common mechanism of toxicity with other substances and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA determined that copper and zinc naphthenate salts may leach from treated wood and are likely to persist in water and soils around the treated wood. They are moderately toxic to freshwater fish and highly toxic to freshwater invertebrates.

Naphthenate salts have a potential for bioaccumulation based on the estimated K_{ow} of 4.17 for copper naphthenate. In order to characterize the bioaccumulation potential of naphthenate salts a fish bioconcentration study is required as a condition of continued registration (Appendix I).

The risk to aquatic and terrestrial species from the use of naphthenate salts as a wood preservative was assessed by the USEPA by calculating risk quotients (RQs), based on appropriate toxicity end-points and expected environmental concentrations (EECs), and by comparing the resulting RQs to corresponding levels of concern (LOCs).

The EECs for naphthenate salts were developed by modeling the release of naphthenate salts into water from a dock (10m x 30m) built with treated wood. It was assumed that 3% of total applied copper naphthenate would leach from the treated wood into the water. The USEPA assessment resulted in EECs of 1.67 ppm for a small body of water (0.3 m) and 0.278 ppm for a larger body of water (1.8 m deep).

The USEPA determined that the acute risk to freshwater species was dependent on the size of the water body. For a small body of water, the acute LOC of 0.5 was exceeded for both freshwater invertebrates and fish. While for a large body of water, the acute LOC was exceeded for freshwater invertebrates only. The USEPA concluded that the risk to aquatic organism is likely to be overestimated since it is highly unlikely that a dock of the size of the one used in the risk assessment will be placed in a body of water less than 1.8 m deep.

The USEPA did not assess the risk to estuarine/marine species or to aquatic and terrestrial plants due to the lack of toxicity data.

The USEPA conclusions pertaining to environmental exposure are considered relevant to the Canadian situation. The PMRA believes that the risk for estuarine/marine species will be negligible based on the registered use pattern for copper and zinc naphthenate salts. No further mitigation measures are required at this time. However, based on general practices, the PMRA is proposing improvements to the general environmental label statements for all end-use product labels. The proposed label statements are listed in Appendix IV.

3.3 Pest Control Product Policy Considerations

3.3.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances (those that meet all four criteria outlined in the policy, namely, CEPA-toxic or equivalent, predominantly anthropogenic, persistent and bio-accumulative.

During the re-evaluation process, copper and zinc naphthenate salts were assessed in accordance with the PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy,* and evaluated against the Track 1 criteria for persistence and bioaccumulation. In order for copper and zinc naphthenate salts to meet Track 1 criteria, the criteria for both bioaccumulation and persistence (in one media) must be met. The PMRA determined that naphthenate salts do not meet the criterion for bioaccumulation based on the estimated *n*-octanol–water partition coefficient (log K_{ow}) of 4.17 for copper naphthenate which is below the TSMP Track 1 criterion (log $K_{ow} \geq 5.0$).

On this basis, it is concluded that the use of copper and zinc naphthenate salts are not expected to result in the entry of Track 1 substances in the environment.

3.3.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of naphthenate salts, contaminants in the technical are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*. The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03; and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

- Technical grade naphthenate copper does not contain any contaminants of health or environmental concern identified in the *Canada Gazette.*

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.

4.0 Organization for Economic Co-operation and Development Status of Naphthenate Salts

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which groups 30 member countries and provides governments with a setting in which to discuss, develop and perfect economic and social policies. They compare experiences, share information and analyses, seek answers to common problems, and work to co-ordinate domestic and international policies to allow for consistency in practices across nations.

Currently, copper and zinc naphthenate salts are authorized for use in the European Union.

As described earlier in this document, the United States, also an OECD member, assessed the registration of all uses of copper and zinc naphthenate salts in 2007 and concluded that using copper or zinc naphthenate as pesticides do not result in unreasonable adverse effects to human health or the environment provided the risk-reduction measures recommended in the RED document were implemented.

The Canadian re-evaluation of copper and zinc naphthenate salts is largely based on the 2007 USEPA assessments and includes additional assessments if applicable. The PMRA has found the USEPA human health and environmental risk conclusions to be relevant to the use of naphthenate salts in Canada and requires measures to further protect workers, individuals in residential settings and the environment.

5.0 Proposed Re-evaluation Decision

The PMRA has determined that copper and zinc naphthenate salts are acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are proposed to further protect human health and the environment:

- Additional personal protective equipment for workers handling copper naphthenate products and for individuals handling domestic products
- Reduction of the maximum guarantee for zinc naphthenate in domestic products
- Restrict copper naphthenate-treated fabric uses to non-residential areas
- Removal of the fabric use from domestic product labels
- Hazard label statements for all end-use products
- General advisory environmental label statements

The labels of Canadian end-use product must be amended to include the label statements listed in Appendix IV.

It should be noted that for end-use products containing more than one active ingredient under re-evaluation, registration status might change as a result of the re-evaluation of the remaining affected active ingredients.

6.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on the Pesticides and Pest Management portion of Health Canada's website at www.healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for Copper and Zinc Naphthenate Salts is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

λ_{max}	maximum wavelength
a.i.	active ingredient
amu	atomic mass unit
bw	body weight
CAS	Chemical Abstracts Service
CEPA	*Canadian Environmental Protection Act*
DACO	data code
EEC	expected environmental concentration [also estimated environmental concentration]
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LOAEL	lowest observed adverse effect level
LOC	level of concern
m	metre(s)
mg	milligram(s)
MOE	margin of exposure
nm	nanometre
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PHED	Pesticide Handlers Exposure Database
PMRA	Pest Management Regulatory Agency
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
RQ	risk quotient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency
UV	ultraviolet

Appendix I Additional Data Requirement

The following data will are required as a condition of continued registration under section 12 of the PCPA. The registrants of technical copper naphthenate and zinc naphthenate will be required to provide these data or an acceptable scientific rationale within the timeline specified in the decision letter that will be sent when a re-evaluation decision is made.

DACO 9.5.6 Bioaccumulation study in fish (both copper and zinc naphthenate)

Appendix II Registered Products Containing Copper and Zinc Naphthenate Salts as of 18 March 2010

Table 1 Copper Naphthenate Products

Registration Number	Marketing Type	Registrant	Product Name	Formulation Type	Guarantee
18119	Technical	OMG Belleville Ltd.	8% Copper Naphthenate	Solution	8% copper
21298	Technical	IBC Manufacturing Co.	Technical Copper Napthenate Wood Preservative	Solution	80% CUN (8% copper)
27151	Technical	Merichem Chemicals & Refinery Services LLC	Cunap-8 Technical	Solution	68% CUN (8% copper)
21859	Commercial	North Star Structural Contractors Ltd.	Cu-89 Wood Preservative Solution	Solution	80% CUN (8% copper)
21860	Commercial	North Star Structural Contractors Ltd.	Cu-89-RTU	Solution	20% CUN (2% copper)
22083	Commercial	IBC Manufacturing Co.	Curap 20 Wood Preservative Paste	Paste	2% copper
23582	Commercial	Genics Inc.	Cobra Wrap	Impregnated fabric	22.25% CUN (2% copper)
23962	Commercial	IBC Manufacturing Co.	Cunapsol-5 Wood Preservative	Solution	50% CUN (5% copper)
25416	Commercial	Genics Inc.	Cobra Wrap SD Wood Preservative	Impregnated fabric	2% copper
25708	Commercial	North Star Structural Contractors Ltd.	Cop-R-Plastic Wood Preserving Compound	Paste	2% copper
27026	Commercial	IBC Manufacturing Co.	Curap 20 Pak Wood Preservative Wrap	Paste	1.6% copper
27409	Commercial	Merichem Chemicals & Refinery Services LLC	Cunap-8 Wood Preservative	Solution	68% CUN (8% copper)
5565	Domestic	Osmose-Pentox Inc.	Pentox Wood Preservative Green	Solution	2.35% copper
10781	Domestic	Recochem Inc.	Copper II Green Preservative Paintable	Solution	8% CUN (2% copper)

Registration Number	Marketing Type	Registrant	Product Name	Formulation Type	Guarantee
12375	Domestic	Osmose-Pentox Inc.	Pentox Cop-R-Nap Green Wood Preservative Green	Solution	2% copper
15013	Domestic	Akzo Nobel Canada Inc.	Polyprep 774-477 Wood Preservative	Solution	8% CUN (2% copper)
15607	Domestic	Home Hardware Stores Ltd.	Home Brand Green Preservative For Wood, Rope, Canvas	Solution	8% CUN (2% copper)
18972	Domestic	Osmose-Pentox Inc.	Osmose End Cut Wood Preservative (Moss)	Solution	2.35% copper
19313	Domestic	Denalt Paints Ltd.	Denalt Wood Preservative	Solution	2% copper
19440	Domestic	Recochem Inc.	Recochem End Cut Preservative Green	Solution	8% CUN (2% copper)
19546	Domestic	Timber Specialties Co.	Greatwood End Cut Wood Preservative	Solution	2.35% copper
20111	Domestic	Korzite Coatings Inc.	Korzite Green Wood Preserver	Solution	2% copper
28527	Domestic	Genics Inc.	Genics Cunap	Solution	2% copper
28874	Domestic	Akzo Nobel Canada Inc.	Sico 774555	Solution	2% copper

Table 2 Zinc Naphthenate Products

Registration Number	Marketing Type	Registrant	Product Name	Formulation Type	Guarantee (% w/w)
18120	Technical	OMG Belleville Ltd.	8% Zinc Naphthenate	Solution	8% zinc
15010	Domestic	Akzo Nobel Canada Inc.	Polyprep 774-188 Wood Preservative	Solution	8% ZNN (2% zinc)
15800	Domestic	Recochem Inc.	Clear Wood Preservative/Brown Wood Preservative	Solution	8% ZNN (2% zinc)
17204	Domestic	Osmose-Pentox Inc.	Pentox Zin-K-Nap Clear Wood Preservative	Solution	2% zinc
18266	Domestic	Home Hardware Stores Ltd.	Home Brand Clear Preservative For Wood, Rope, Canvas	Solution	8% ZNN (2% zinc)
19493	Domestic	Osmose-Pentox Inc.	Osmose End Cut Wood Preservative Tan	Solution	2.35% zinc
19545	Domestic	Timber Specialties Co.	Endcoat Wood Preservative - Brown	Solution	2% zinc
19547	Domestic	Timber Specialties Co.	Endcoat Wood Preservative - Soft Green	Solution	2% zinc
20112	Domestic	Korzite Coatings Inc.	Korzite Clear Wood Preserver	Solution	2% zinc
22859	Domestic	Timber Specialties Co.	Silvertone Endcoat Wood Preservative	Solution	2% zinc
24351	Domestic	Produits Chimiques Techni-Seal	Wood Preservative	Solution	25% ZNN (2% zinc)
28873	Domestic	Akzo Nobel Canada Inc.	Sico 774-444	Solution	2% zinc

Appendix III Toxicological Endpoints for Copper and Zinc Naphthenate Salts Health Risk Assessments

Exposure Scenario (route and period of exposure)	Dose (mg/kg bw/day)	Study	Target MOE[a]
Incidental oral (residential)	Oral NOAEL=30 mg/kg bw/day (maternal)	Developmental toxicity study in the rat (CUN) Based on decreased body weight and food consumption observed at LOAEL of 100 mg/kg bw/day	Target MOE 100 (10 fold interspecies and 10 fold intraspecies variations)
Short term/ Intermediate term dermal (residential, occupational) **Zinc naphthenate only**	Dermal NOAEL=100mg/kg bw/day	90-day dermal toxicity study in the rabbit (ZNN) Based on reduction in body weight gain observed at LOAEL of 300 mg/kg bw/day	Target MOE 100 (10 fold inter and 10 fold intraspecies variations)
All term Inhalation (residential and occupational)	Oral NOAEL=30 mg/kg bw/day	Developmental toxicity study in the rat (CUN) Based on decreased body weight and food consumption observed at LOAEL of 100 mg/kg bw/day	Target MOE 1000 (10 fold interspecies and 10 fold intraspecies variations and 10-fold route extrapolation)
Cancer	Not classified		

a MOE refers to desired margin of exposure for occupational or residential assessments.

Appendix IV Proposed Label Amendments for Products Containing Copper and Zinc Naphthenate Salts

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect human health and the environment.

I) For commercial wood and material preservative uses of copper naphthenate, the following statements must be included in the **PRECAUTIONS** section.

> Causes skin and eye irritation. Potential skin sensitizer. Do not get in eyes, on skin or on clothing. Workers must wear coveralls over a long-sleeved shirt and long pants, chemical resistant footwear, chemical resistant gloves and goggles during loading, clean-up and repair. In addition, a respirator is required for workers applying copper products by brush.

II) For the commercial material preservative use of copper naphthenate, the following statements must be included in the **DIRECTIONS FOR USE** section.

> DO NOT use on any fabric where prolonged skin contact may occur. Treated textiles preserved with copper naphthenate are not to be used in residential settings where bystanders including children may potentially contact treated textiles. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public including children could be exposed.

III) For the commercial wood preservation use of copper naphthenate, the following statements must be included in the **DIRECTIONS FOR USE** section.

> DO NOT apply using an airless sprayer.
>
> DO NOT apply this product to wood that will be used in water.

IV) The fabric use must be removed from all labels of domestic end-use products containing copper naphthenate or zinc naphthenate.

V) For the zinc naphthenate wood preservative use, the maximum guarantee on the domestic label must not exceed 16% zinc naphthenate (2% zinc as elemental) The label of end-use product Registration Number 24351 must be amended to reflect this reduction.

VI) For domestic products containing copper naphthenate or zinc naphthenate, the following statement must be included in the **PRECAUTIONS** section.

> Causes skin and eye irritation. Potential skin sensitizer. Avoid, breathing vapours, contact with skin, eyes and clothing. Wear a long-sleeved shirt, long pants, socks, shoes and rubber gloves when applying this product.

VII) For all products containing copper naphthenate or zinc naphthenate, the following statements must be included on a primary panel.

> WARNING EYE AND SKIN IRRITANT
>
> POTENTIAL SKIN SENSITIZER

VIII) For technical and commercial products containing copper naphthenate, the following statement must be included in the **DIRECTIONS FOR USE** section.

> DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans and other waters.

IX) For all commercial and domestic products containing copper naphthenate or zinc naphthenate, the following statement must be included in the **DIRECTIONS FOR USE** section.

> DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

X) For all commercial and domestic products containing copper naphthenate or zinc naphthenate, the following statements must be included in the **ENVIRONMENTAL HAZARDS** section.

> Toxic to aquatic organisms.

References

Information Considered for the Chemistry Assessment

Studies/Information Submitted by Applicant/Registrant (Unpublished)

PMRA Document Number: 1262623
Reference: Product Chemistry for Copper Naphthenate Technical. Data Numbering Code: 2.0 Confidential Business Information.

PMRA Document Number: 1537261
Reference: Physical and Chemical properties. Manufacturing methods. Data Numbering Code: 2.11.2, 2.11.3 Confidential Business Information.